

U.S. Application No.: 09/438,759
AMENDMENT F

Attorney Docket: 2368/098

REMARKS

Review and reconsideration of the Office Action dated March 22, 2004, is respectfully requested in view of the above amendments and the following remarks.

Applicants are pleased to see that the Examiner withdrew all his previous rejections.

The claims have been amended to consistently refer to element 10 as a hollow tube, and to limit the catheter to a flexible catheter.

In addition, applicants have added new Claim 42 which is equivalent to Claim 1 of the corresponding European Patent EP 966922 B1. Support for Claim 42 can be found in the last paragraph of page 6.

Applicants believe that the claims are novel in view of the new cited reference.

Applicants note that the present invention is directed to a unipolar cannula, i.e. the cannula has only one electrode. A **unipolar cannula** (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

Applicants reviewed the '994 reference (main reference) and note that the reference teaches a two part trocar needle designed to measure the electrical **impedance** of the tissue at the tip of the trocar. A trocar is used to penetrate the tissue to provide a channel for a subsequent access for endoscopic examination or the like. (column 1, lines 19-28).

In order to avoid accidental puncture of anatomical structure during insertion the actual position of the trocar needle tip is detected by measurement of the electrical impedance of the tissue adjacent to the tip of the trocar needle. For the measurement of the impedance the tip **must have two electrodes**. Therefore, the trocar needle of the '994 reference has to be **bipolar with an electrically conductive trocar sleeve and an electrically conductive inner stylet** thus the trocar sleeve and the stylet simultaneously penetrate the tissue and the trocar sleeve and the stylet both have a non-insulated tip contacting the tissue and forming the two electrodes for measuring the impedance there between.

Compared with independent Claims 27, 34, 38, and 41, the '994 reference fails to teach: 1) **flexible catheter**; 2) the tip of the electrically conductive rigid hollow tube is **dimensioned for passage of the catheter**; 3) the inlet opening guides the catheter for introduction into the proximal end of the hollow tube (10); 4) a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation; 5) and an unipolar cannula.

The Present Invention

The present invention is concerned with the task of providing a **unipolar cannula** for continuous anesthesia, which through simple construction and simple operation unites:

- (a) the ability to place a catheter,
- (b) the ability to administer anesthetic,
- (c) no need for separate electrical conductors to supply electricity for electro-stimulation to the tip of the catheter, since the body of the catheter is used as a conductor, and
- (d) the advantage of very precise electro-stimulation.

Where it was previously necessary to, e.g., simultaneously introduce a hose for anesthetic and a separate unipolar canula into a plastic cannula tube, the inventive unipolar **cannula** can be placed or located with the help of electrical nerve stimulation. The outer insulating covering of the cannula tube, which leaves only a very small, almost pinpoint area of the tip free, makes possible an extraordinarily precise placement of the tip. The unipolar **cannula** can itself be used for the guided introduction of the **catheter**. The connection for electro-stimulation is introduced through the side of the body part and contacts the outside of the electrically conductive cannula tube. This manner of connection does not impede or constrict therewith the axial inlet opening of the body part. After the placement of the unipolar cannula with the help of electro-stimulation, the catheter can be introduced through the cannula tube, without any requirement that the position of the unipolar cannula must be changed or other measures be taken.

Preferably, a releasable or removable connection is formed with the body part at the introduction opening, preferably a

U.S. Application No.: 09/438,759

AMENDMENT F

Attorney Docket: 2368/098

Preferably, a releasable or removable connection is formed with the body part at the introduction opening, preferably a Luer-lock connection (Claim 32). At this connection, an injection hose can be connected, if desired, for injection of an initial or a short duration anesthetic. Likewise, a needle can be connected to the releasable connection, for injection of an anesthetic or also for fluids for aspiration for position control.

The possibility of using the body part both for the alternative connection of an injection hose or a needle as well as for introduction of the catheter makes the unipolar cannula extremely versatile. This versatility is achieved using an extremely simple and economical design. The manipulation of the unipolar cannula is likewise extremely simple, since the cannula can be employed without changing the position both for the injection or aspiration as well as for the introduction of the catheter. The axially aligned connection of a needle at the proximal body part makes possible also the carrying out of the nerve block with a one-hand technique.

Paragraph 1 (Obviousness)

The Examiner rejects Claims 27, 30-35, 38 ;39 and 41 under 35 U.S.C. 103(a) as being obvious over Stoianovici et al., 6,337,994, in view of Wojciechowicz, 5,730,742.

The position of the Examiner can be found on pages 2-4 of the office action.

Applicants respectfully traverse.

U.S. Application No.: 09/438,759
AMENDMENT F

Attorney Docket: 2368/098

Regarding the '994 reference

Compared with independent Claims 27, 34, 38, and 41, the '994 reference fails to teach: 1) **flexible** catheter; 2) the tip of the electrically conductive rigid hollow tube is **dimensioned for passage of the catheter**; 3) the inlet opening guides the catheter for introduction into the proximal end of the hollow tube (10); 4) a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation; 5) and an unipolar cannula.

Regarding point 1

Applicants reviewed the reference and note that the reference is directed to an electrical impedance probe including a surgical needle. The probe presents a two part construction comprising an outer sleeve 12 and an inner stylet. The stylet has a sharp end tip. Furthermore, the probe includes an insulation cover 34.

Applicants note that the Examiner is of the wrong opinion that element 14 of the reference (stylet) is equivalent to the catheter of the present invention.

According to the Dictionary, the term "stylet" means a slender (slim), pointed instrument or weapon.

According to the Dictionary, "Catheter" means a **hollow flexible tube** for insertion into a body cavity, duct, or vessel

U.S. Application No.: 09/438,759

AMENDMENT F

Attorney Docket: 2368/098

to allow the passage of fluids or distend a passageway. Its uses include the drainage of urine from the bladder through the urethra or insertion through a blood vessel into the heart for diagnostic purposes.

Furthermore, Applicants note that the stylet of the reference is made of metal, and metal cannot be considered flexible.

Regarding points 2-3

Because the term "stylet" means a slender (**slim**), pointed instrument or weapon, a person skilled in the art cannot consider that the stylet of the reference can have a tip big enough to allow the passage of a catheter.

The Examiner is of the opinion that Figure 2 shows that the stylet 14 is dimensioned to allow the passing of a catheter. Applicants reviewed Figure 2 and note that the element being introduced into the stylet is a connector and not a catheter as indicated by the Examiner.

Furthermore, nowhere in the reference can be found the teaching that there is an inlet opening that guides the catheter for introduction into the proximal end of the hollow tube.

Regarding point 4

According to the Examiner, the reference teaches in column 6, lines 43-50, that the connector is connected to the hollow tube (10) in the area of the body part. We reviewed the text

pointed out by the Examiner and cannot find any of the teaching indicted by the Examiner. Furthermore, the review of Figure 7 indicated that the connector is attached to the outer sleeve 12, which according to the Examiner's own words is equivalent to the hollow body of the present invention. This is a major structural difference between the present invention and the cited reference.

Regarding point 5

Applicants note that the present invention is directed to a unipolar cannula, i.e. the cannula has only one electrode. A **unipolar cannula** (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

The reference includes two electrodes, column 3, lines 37-41.

Applicants reviewed the '994 reference and note that the reference teaches a two part trocar needle designed to measure the electrical impedance of the tissue at the tip of the trocar. A trocar is used to penetrate the tissue to provide a channel for a subsequent access for endoscopic examination or the like. (column 1, lines 19-28).

In order to avoid accidental puncture of anatomical structure during insertion the actual position of the trocar needle tip is detected by measurement of the electrical impedance of the tissue adjacent to the tip of the trocar needle. For the measurement of the impedance the tip must have two electrodes.

Therefore, the trocar needle of the '994 reference has to be bipolar with an electrically conductive trocar sleeve and an electrically conductive inner stylet whereby the trocar sleeve and the stylet simultaneously penetrate the tissue and the trocar sleeve and the stylet both have a non-insulated tip contacting the tissue and forming the two electrodes for measuring the impedance there between.

Contrary to the '994 reference, the present invention relates to a unipolar cannula for anesthesia. The cannula is inserted into the nerve sheath and the tip of the cannula is positioned by stimulating the nerve electrically. During the insertion of the cannula and the positioning of the tip, there is no catheter inside the cannula. After the tip of the cannula is positioned by the unipolar stimulation the flexible catheter is introduced through the cannula into the nerve sheath whereby no electrical satimualtion is necessary and therefore the flexible catheter has not to be electrically conductive.

The '994 reference shows a two part trocar needle with electrically conductive rigid outer tube and an electrically conductive rigid inner stylet. Both parts simultaneously penetrate the tissue and the electrical impedance between the tip of the outer tube and the tip of the stylet is measured bipolar. According to the invention, there is only one electrically conductive cannula tube for an unipolar electro stimulation of the nerve. A flexible catheter which is not electrically conductive is introduced through the cannula after the tip of the cannula is positioned by the electro stimulation.

Figure 2 of the '994 reference shows schematically the outer tube and the inner stylet but not a stylet with a flexible catheter. However, the Examiner is correct in that the stylet of the '994 reference must not have a sharp tip. In column 2, lines 8-11, it is noted that the inner stylet is not necessarily pointed but may be a blunt obturator. However, in any case, the inner stylet has to be electrically conductive and rigid so it cannot be flexible catheter of plastic.

Furthermore, nowhere in the reference can be found the teaching that the probe measures electro stimulation. The reference is directed to measure **impedance**.

Regarding the '742

The Examiner cited the '742 reference to show that the cannula is formed from steel.

Applicants reviewed the '742 reference and note that compared with the independent claims, the reference fails to teach: 1) a unipolar cannula, and 2) a flexible catheter and a cannula **in the same device**; and 3) a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation.

Applicant's position regarding this reference can be found in the responses to the previous office actions. Applicants only have to say that this reference does not overcome the deficiencies of the '994 reference.

Combining the references

Neither of the references taken alone or in combination teaches all the elements of the present set of claims. Thus, even if the references are combined, they will not teach the present invention.

It is impermissible within the framework of section 103 to **pick and choose** from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."

The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. Evidence of such motivation may "flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved."

In the present case, the Examiner failed to point out where in the '994 reference can be found the teaching of using a cannula made of a conductive metal.

Using an applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of § 103 which requires judging obviousness at the point in time when the

U.S. Application No.: 09/438,759

AMENDMENT F

Attorney Docket: 2368/098

invention was made. See Grain Processing Corp. v. American Maize- Prods. Co., 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

If a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. See In re Fritch, 972 F.2d at 1265 n.12, 23 U.S.P.Q.2d at 1783 n.12 ("A proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the prior art reference inoperable for its intended purpose."); In re Ratti, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959) (holding the suggested combination of references improper under § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate").

In addition, if the references are combined, it "would require a substantial reconstruction and redesign of the elements shown in the '994 reference, as well as a change in the basic principles under which that reference's construction was designed to operate." Thus, a person skilled in the art will not consider combining the references.

Accordingly, withdrawal of the rejections is respectfully requested.

U.S. Application No.: 09/438,759
AMENDMENT F

Attorney Docket: 2368/098

Paragraph 2 (Obviousness)

The Examiner rejects Claims 28 and 29 under 35 U.S.C. 103(a) as being obvious over Stoianovici et al., 6,337,994, in view of Mower et al., 4,765,341.

The position of the Examiner can be found on page 5 of the Office Action.

Applicants respectfully traverse for the same reasons as set forth in paragraph 1 and the following remarks:

The '341 reference shows an implantable cardiac electrode for defibrillation. Therefore, this reference cannot give any teaching for the electrical connection of a cannula tube.

Claims 28 and 29 are directed to a special way of contacting the electrically conductive tube of the cannula with the stimulating wire. Because electrically conductive soldering of steel is difficult, the contact is formed according to claims 28 and 29.

In addition, Applicants note that Claims 28 and 29 depend on Claim 27, thus these claims are novel in view of their dependency with novel Claim 27.

Accordingly, withdrawal of the rejections is respectfully requested.

U.S. Application No.: 09/438,759
AMENDMENT F

Attorney Docket: 2368/098

Paragraph 3 (Obviousness)

The Examiner rejects Claims 36, 37, and 40 under 35 U.S.C. 103(a) as being obvious over Stoianovici et al., 6,337,994, in view of Haindl, 4,889,529.

The position of the Examiner can be found on pages 5-6 of the Office Action.

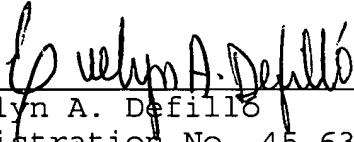
Applicants respectfully traverse for the same reasons as set forth in paragraph 1 and the following remarks:

In addition, Applicants note that these claims depend on Claim 27, thus these claims are novel in view of their dependency with novel Claim 27.

Accordingly, withdrawal of the rejections is respectfully requested.

Favorable consideration and early issuance of the Notice of Allowance is respectfully requested.

Respectfully submitted,



Evelyn A. Defillio

Registration No. 45,630

PENDORF & CUTLIFF
5111 Memorial Highway
Tampa, Florida 33634-7356
(813) 886-6085

Date: September 20, 2004